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EXAMINER	
BEISNER, WILLIAM H	

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1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,559	WILLSON ET AL.	
	Examiner	**Art Unit**	
	WILLIAM H. BEISNER	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _02 March 2009_.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _50,76,99-101,103-105,108-111,113-115 and 119-122_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _50,76,99-101,103-105,108-111,113-115 and 119-122_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 50, 99-101, 103-105, 108, 119 and 121 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 50 recites the new claim limitation of "randomly placing the sensing elements in a liquid composition comprising one or more analytes". While the originally filed disclosure discusses random placement of the sensing elements on a support structure, the originally filed disclosure is silent with respect to this newly recited claim limitation.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 50, 99, 100 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view of Peters, Jr. et al.(US 5,013,669).

The reference of Walt et al. discloses a method of sensing multiple analytes in a fluid that includes passing a fluid over a sensor array wherein the sensor array includes a plurality of sensing elements coupled to a supporting member, wherein a first portion of the sensing elements are configured to produce a signal in the presence of a first analyte and wherein a

second portion of the sensing elements are configured to produce a signal in the presence of a second analyte. The first and second portions of the sensing elements have unique predetermined optical signatures or tags wherein the optical signature or tag of the first portion of sensing elements is different from the optical signature or tag of the second portion of sensing elements. The method includes monitoring a spectroscopic change of the sensing elements as the fluid is passed over the sensing array, wherein the spectroscopic change is caused by the interaction of the analyte with the sensing element and determining the unique optical signature of the sensing elements that undergo a spectroscopic change (See column 13, lines 8-24, and column 15, line 64, to column 16, line 20).

With respect to claim 50, while the reference of Walt et al. disclose the use of unique predetermined optical signatures or tags that include the use of beads of different size (See column 18, lines 48-58, and column 19, lines 6-13), claim 50 differs by reciting that the method employs sensing elements (beads) of different shapes wherein the sensing element undergoing a spectroscopic change is identified by its shape.

The reference of Felder et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 8, lines 49-56).

The reference of Chang et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 3, lines 33-39).

The reference of Ravkin et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See paragraphs [0096], [0137] and [0139]).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a unique optical signature with respect to the beads of the primary reference of Walt et al. using beads of different shapes for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a means for optically distinguishing one sensing element from another. Use of beads of different shape rather than size would eliminate the need to employ different sized optical fibers required to detect the beads of different size. The same types of optical fibers would be capable of detecting beads of similar size but different shapes. Note if beads of different shape are not considered to be different "geometric" shapes, one of ordinary skill in the art in view of the teachings of Felder et al., Chang et al. or Ravkin et al. would have envisioned the use of different shapes for achieving the same result, detection of an analyte based on the shape of the sensing element rather than the location of the sensing element.

While the reference of Walt et al. discloses the use of porous polymer beads (See column 7, lines 20-41) and the use of a number of receptors that can be attached to the beads (See column 7, line 55, to column 12, line 62) the reference does not specifically disclose that the receptors are at least partially encapsulated within the polymer material forming the sensing elements.

The reference of Peters, Jr. et al. discloses that it is conventional in the art to encapsulate receptor molecules (See column 8, lines 54-67) within the pores of porous polymer bodies (See

column 6, line 53, to column 7, line 37). The receptors are encapsulated within the pores of the bodies using a polymer (See column 7, line 48, to column 8, line 53).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to encapsulate the receptors of modified primary reference using the method disclosed by the reference of Peters, Jr. et al. for the known and expected results of avoiding the disadvantages associated with other known techniques for attaching the receptors to the solid support material (See column 1, line 5, to column 3, line 37).

Note the reference of Walt et al. discloses that the sensing elements (microspheres) are randomly places (See column 15, lines 64-66). As a result, the modified sensing elements would also be randomly placed.

With respect to claim 99, the sensing elements are placed near the surface of the liquid composition (See column 17, line 47, to column 18, line 2).

With respect to claim 100, the reference of Walt et al. discloses that the sensing elements can be made from a polymer (See column 7, lines 20-41).

With respect to claim 108, the receptors can be a nucleic acid (See column 7, line 55, to column 8, line 3).

7. Claims 50, 99, 100 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view of Kaetsu et al.(US 4,194,066).

The reference of Walt et al. discloses a method of sensing multiple analytes in a fluid that includes passing a fluid over a sensor array wherein the sensor array includes a plurality of sensing elements coupled to a supporting member, wherein a first portion of the sensing elements are configured to produce a signal in the presence of a first analyte and wherein a second portion of the sensing elements are configured to produce a signal in the presence of a second analyte. The first and second portions of the sensing elements have unique predetermined optical signatures or tags wherein the optical signature or tag of the first portion of sensing elements is different from the optical signature or tag of the second portion of sensing elements. The method includes monitoring a spectroscopic change of the sensing elements as the fluid is passed over the sensing array, wherein the spectroscopic change is caused by the interaction of the analyte with the sensing element and determining the unique optical signature of the sensing elements that undergo a spectroscopic change (See column 13, lines 8-24, and column 15, line 64, to column 16, line 20).

With respect to claim 50, while the reference of Walt et al. disclose the use of unique predetermined optical signatures or tags that include the use of beads of different size (See column 18, lines 48-58, and column 19, lines 6-13), claim 50 differs by reciting that the method employs sensing elements (beads) of different shapes wherein the sensing element undergoing a spectroscopic change is identified by its shape.

The reference of Felder et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 8, lines 49-56).

The reference of Chang et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 3, lines 33-39).

The reference of Ravkin et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See paragraphs [0096], [0137] and [0139]).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a unique optical signature with respect to the beads of the primary reference of Walt et al. using beads of different shapes for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a means for optically distinguishing one sensing element from another. Use of beads of different shape rather than size would eliminate the need to employ different sized optical fibers required to detect the beads of different size. The same types of optical fibers would be capable of detecting beads of similar size but different shapes. Note if beads of different shape are not considered to be different "geometric" shapes, one of ordinary skill in the art in view of the teachings of Felder et al., Chang et al. or Ravkin et al. would have envisioned the use of different shapes for achieving the same result, detection of an analyte based on the shape of the sensing element rather than the location of the sensing element.

While the reference of Walt et al. discloses the use of porous polymer beads (See column 7, lines 20-41) and the use of a number of receptors that can be attached to the beads (See column 7, line 55, to column 12, line 62) the reference does not specifically disclose that the

receptors are at least partially encapsulated within the polymer material forming the sensing elements.

The reference of Kaetsu et al. discloses that is it known in the art to form porous polymer particles that include biological active materials by mixing a monomer and the receptors prior to forming the final porous body (See column 3, lines 10-53) wherein the biological active material (receptor) is at least partially encapsulated in the polymer body formed.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to encapsulate the receptors of modified primary reference using the method disclosed by the reference of Kaetsu et al. for the known and expected results of avoiding the disadvantages associated with other known techniques for encapsulating or attaching the receptors to the solid support material (See column 1, line 5, to column 2, line 7).

Note the reference of Walt et al. discloses that the sensing elements (microspheres) are randomly places (See column 15, lines 64-66). As a result, the modified sensing elements would also be randomly placed.

With respect to claim 99, the sensing elements are placed near the surface of the liquid composition (See column 17, line 47, to column 18, line 2).

With respect to claim 100, the reference of Walt et al. discloses that the sensing elements can be made from a polymer (See column 7, lines 20-41).

With respect to claim 108, the receptors can be a nucleic acid (See column 7, line 55, to column 8, line 3).

8. Claims 50, 76, 99-100, 103, 108, 109, 111, 113, 119 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view of Pope (US 5,496,997) and Dakss et al.(US 4,269,648) and taken further in view of Peters, Jr. et al.(US 5,013,669).

The reference of Walt et al. discloses a method of sensing multiple analytes in a fluid that includes passing a fluid over a sensor array wherein the sensor array includes a plurality of sensing elements coupled to a supporting member, wherein a first portion of the sensing elements are configured to produce a signal in the presence of a first analyte and wherein a second portion of the sensing elements are configured to produce a signal in the presence of a second analyte. The first and second portions of the sensing elements have unique predetermined optical signatures or tags wherein the optical signature or tag of the first portion of sensing elements is different from the optical signature or tag of the second portion of sensing elements. The method includes monitoring a spectroscopic change of the sensing elements as the fluid is passed over the sensing array, wherein the spectroscopic change is caused by the interaction of the analyte with the sensing element and determining the unique optical signature of the sensing elements that undergo a spectroscopic change (See column 13, lines 8-24, and column 15, line 64, to column 16, line 20).

With respect to claim 76, while the reference of Walt et al. disclose the use of unique predetermined optical signatures or tags that include the use of beads of different size (See column 18, lines 48-58, and column 19, lines 6-13), claim 76 differs by reciting that the method

employs sensing elements (beads) of different shapes wherein the sensing element undergoing a spectroscopic change is identified by its shape.

The reference of Felder et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 8, lines 49-56).

The reference of Chang et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 3, lines 33-39).

The reference of Ravkin et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See paragraphs [0096], [0137] and [0139]).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a unique optical signature with respect to the beads of the primary reference of Walt et al. using beads of different shapes for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a means for optically distinguishing one sensing element from another. Use of beads of different shape rather than size would eliminate the need to employ different sized optical fibers required to detect the beads of different size. The same types of optical fibers would be capable of detecting beads of similar size but different shapes. Note if beads of different shape are not considered to be different "geometric" shapes, one of ordinary skill in the art in view of the teachings of Felder et al., Chang et al. or Ravkin et al. would have envisioned

the use of different shapes for achieving the same result, detection of an analyte based on the shape of the sensing element rather than the location of the sensing element.

With respect to Claim 76, while the reference of Walt et al. discloses that immobilization of the different sensing elements to substrate (212) to form a sensing array includes placing the sensing elements in a liquid composition and curing the liquid composition to form a supporting member, wherein the sensing elements are at least partially embedded within the cured liquid composition (See column 17, line 47, to column 18, line 2), the claim further differs by reciting that the sensing elements are disposed **on or at an exterior surface of a cured liquid composition** for supporting the sensing elements.

The reference of Pope discloses that it is conventional in the art to immobilize an analysis particle (311) with respect to an optical fiber (312) using an adhesive composition (315).

The reference of Dakss et al. discloses that it is known in the art to immobilize a particle (11) with respect to an optical fiber (16) using a cured liquid composition (14) wherein the particle is disposed on or at the exterior surface of the cured liquid composition (See column 3, lines 20-40).

In view of these disclosures, it would have been obvious to one of ordinary skill in the art to immobilize the analysis particles of the modified primary reference using a cured liquid composition as suggested by the references of Pope and Dakss et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, immobilization of the analysis particles relative to the optical sensing components. This immobilization technique allows the analysis particle to be in direct contact with the test sample.

While the reference of Walt et al. discloses the use of porous polymer beads (See column 7, lines 20-41) and the use of a number of receptors that can be attached to the beads (See column 7, line 55, to column 12, line 62) the reference does not specifically disclose that the receptors are at least partially encapsulated within the polymer material forming the sensing elements.

The reference of Peters, Jr. et al. discloses that it is conventional in the art to encapsulate receptor molecules (See column 8, lines 54-67) within the pores of porous polymer bodies (See column 6, line 53, to column 7, line 37). The receptors are encapsulated within the pores of the bodies using a polymer (See column 7, line 48, to column 8, line 53).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to encapsulate the receptors of modified primary reference using the method disclosed by the reference of Peters, Jr. et al. for the known and expected results of avoiding the disadvantages associated with other known techniques for attaching the receptors to the solid support material (See column 1, line 5, to column 3, line 37).

With respect to claim 50, manufacture of the test device as suggested above would meet the method steps recited in claim 50. Also, the method suggested by Peters, Jr. et al. includes polymerizing a monomer composition. Finally, the reference of Walt et al. discloses a number of receptors that can be used and produce a signal when they interact with an analyte (See column 13, lines 8-57). Note the reference of Walt et al. discloses that the sensing elements (microspheres) are randomly places (See column 15, lines 64-66). As a result, the modified sensing elements would also be randomly placed.

With respect to claim 99, the sensing elements are placed near the surface of the liquid composition (See column 17, line 47, to column 18, line 2).

With respect to claims 100 and 109, the reference of Walt et al. discloses that the sensing elements can be made from a polymer (See column 7, lines 20-41).

With respect to claim 111, the reference of Walt et al. discloses a number of receptors that can be used and produce a signal when they interact with an analyte (See column 13, lines 8-57).

With respect to claims 103 and 113, the modifications suggested in the combination of references discussed above would result in sensing elements that include non-spherical shape.

With respect to claim 108, the receptors can be a nucleic acid (See column 7, line 55, to column 8, line 3).

With respect to claims 119 and 120, the method suggested by the reference of Peters et al. would result in the sensing element being formed using a mixture of monomer and receptor (See column 11, lines 1-30 of Peters, Jr. et al.) to form the desired geometric shape.

With respect to claims 121 and 122, the reference of Dakss et al. employ light curing of the polymer.

9. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view of Pope (US 5,496,997) and Dakss et al.(US 4,269,648); taken further in view of Peters, Jr. et al.(US 5,013,669) and taken further in view of Wang et al.(US 5,922,617).

The combination of the reference of Walt et al. with either Felder et al., Change et al. or Ravkin et al. and further in view of Pope, Dakss et al. and Peters et al. has been discussed above.

While the modified primary reference as discussed above suggests the use of different shaped beads, claim 103 specifies that the shape is a cross, square or triangle.

The reference of Wang et al. discloses when using detection beads similar to that of the modified primary reference, it is known in the art to employ a "square" shape (See Figure 2E).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ any known shape for the detection beads, including a square, as is conventional in the art while providing the expected result of providing a solid support for the receptors of different distinguishable shapes.

10. Claims 50, 76, 99-101, 103-105, 108-111, 113-115, 119 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view of Pope (US 5,496,997) and Dakss et al.(US 4,269,648) and taken further in view of Kaetsu et al.(US 4,194,066).

The reference of Walt et al. discloses a method of sensing multiple analytes in a fluid that includes passing a fluid over a sensor array wherein the sensor array includes a plurality of sensing elements coupled to a supporting member, wherein a first portion of the sensing elements are configured to produce a signal in the presence of a first analyte and wherein a second portion of the sensing elements are configured to produce a signal in the presence of a second analyte. The first and second portions of the sensing elements have unique

predetermined optical signatures or tags wherein the optical signature or tag of the first portion of sensing elements is different from the optical signature or tag of the second portion of sensing elements. The method includes monitoring a spectroscopic change of the sensing elements as the fluid is passed over the sensing array, wherein the spectroscopic change is caused by the interaction of the analyte with the sensing element and determining the unique optical signature of the sensing elements that undergo a spectroscopic change (See column 13, lines 8-24, and column 15, line 64, to column 16, line 20).

With respect to claim 76, while the reference of Walt et al. disclose the use of unique predetermined optical signatures or tags that include the use of beads of different size (See column 18, lines 48-58, and column 19, lines 6-13), claim 76 differs by reciting that the method employs sensing elements (beads) of different shapes wherein the sensing element undergoing a spectroscopic change is identified by its shape.

The reference of Felder et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 8, lines 49-56).

The reference of Chang et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 3, lines 33-39).

The reference of Ravkin et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See paragraphs [0096], [0137] and [0139]).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a unique optical signature with respect to the beads of the primary reference of Walt et al. using beads of different shapes for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a means for optically distinguishing one sensing element from another. Use of beads of different shape rather than size would eliminate the need to employ different sized optical fibers required to detect the beads of different size. The same types of optical fibers would be capable of detecting beads of similar size but different shapes. Note if beads of different shape are not considered to be different "geometric" shapes, one of ordinary skill in the art in view of the teachings of Felder et al., Chang et al. or Ravkin et al. would have envisioned the use of different shapes for achieving the same result, detection of an analyte based on the shape of the sensing element rather than the location of the sensing element.

With respect to Claim 76, while the reference of Walt et al. discloses that immobilization of the different sensing elements to substrate (212) to form a sensing array includes placing the sensing elements in a liquid composition and curing the liquid composition to form a supporting member, wherein the sensing elements are at least partially embedded within the cured liquid composition (See column 17, line 47, to column 18, line 2), the claim further differs by reciting that the sensing elements are disposed **on or at an exterior surface of a cured liquid composition** for supporting the sensing elements.

The reference of Pope discloses that it is conventional in the art to immobilize an analysis particle (311) with respect to an optical fiber (312) using an adhesive composition (315).

The reference of Dakss et al. discloses that it is known in the art to immobilize a particle (11) with respect to an optical fiber (16) using a cured liquid composition (14) wherein the particle is disposed on or at the exterior surface of the cured liquid composition (See column 3, lines 20-40).

In view of these disclosures, it would have been obvious to one of ordinary skill in the art to immobilize the analysis particles of the modified primary reference using a cured liquid composition as suggested by the references of Pope and Dakss et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, immobilization of the analysis particles relative to the optical sensing components. This immobilization technique allows the analysis particle to be in direct contact with the test sample.

While the reference of Walt et al. discloses the use of porous polymer beads (See column 7, lines 20-41) and the use of a number of receptors that can be attached to the beads (See column 7, line 55, to column 12, line 62) the reference does not specifically disclose that the receptors are at least partially encapsulated within the polymer material forming the sensing elements.

The reference of Kaetsu et al. discloses that is it known in the art to form porous polymer particles that include biological active materials by mixing a monomer and the receptors prior to forming the final porous body (See column 3, lines 10-53) wherein the biological active material (receptor) is at least partially encapsulated in the polymer body formed.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to encapsulate the receptors of modified primary reference using the method disclosed by the reference of Kaetsu et al. for the known and expected results of avoiding the disadvantages

associated with other known techniques for encapsulating or attaching the receptors to the solid support material (See column 1, line 5, to column 2, line 7).

With respect to claim 50, manufacture of the test device as suggested above would meet the method steps recited in claim 50. Also, the method suggested by Kaetsu et al. includes polymerizing a monomer composition. Finally, the reference of Walt et al. discloses a number of receptors that can be used and produce a signal when they interact with an analyte (See column 13, lines 8-57). Note the reference of Walt et al. discloses that the sensing elements (microspheres) are randomly places (See column 15, lines 64-66). As a result, the modified sensing elements would also be randomly placed.

With respect to claim 99, the sensing elements are placed near the surface of the liquid composition (See column 17, line 47, to column 18, line 2).

With respect to claims 100 and 109, the reference of Walt et al. discloses that the sensing elements can be made from a polymer (See column 7, lines 20-41).

With respect to claims 101, 104, 105, 110, 114 and 115, the reference of Kaetsu et al. discloses that the polymer body can comprise polyethylene glycol, including polyethylene glycol diacrylate (See column 5, lines 45-50).

With respect to claim 111, the reference of Walt et al. discloses a number of receptors that can be used and produce a signal when they interact with an analyte (See column 13, lines 8-57).

With respect to claims 103 and 113, the modifications suggested in the combination of references discussed above would result in sensing elements that include non-spherical shape.

With respect to claim 108, the receptors can be a nucleic acid (See column 7, line 55, to column 8, line 3).

With respect to claims 119 and 120, the method suggested by the reference of Kaetsu et al.would result in the sensing element being formed using a mixture of monomer and receptor to form the desired geometric shape.

With respect to claims 121 and 122, the reference of Dakss et al. employ light curing of the polymer.

11. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view of Pope (US 5,496,997) and Dakss et al.(US 4,269,648); taken further in view of Kaetsu et al.(US 4,194,066)and taken further in view of Wang et al.(US 5,922,617).

The combination of the reference of Walt et al. with either Felder et al., Change et al. or Ravkin et al. and further in view of Pope, Dakss et al. and Kaetsu et al. has been discussed above.

While the modified primary reference as discussed above suggests the use of different shaped beads, claim 103 specifies that the shape is a cross, square or triangle.

The reference of Wang et al. discloses when using detection beads similar to that of the modified primary reference, it is known in the art to employ a "square" shape (See Figure 2E).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ any known shape for the detection beads, including a square, as is conventional in the art

while providing the expected result of providing a solid support for the receptors of different distinguishable shapes.

Response to Amendment

12. The declaration filed on 8/27/2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Chang and Ravkin references for the following reasons.

The declaration is deficient:

ii) The evidence submitted is insufficient to establish diligence from a date prior to the effective date of Chang and Ravkin references to either a constructive reduction to practice or an actual reduction to practice. Note while the provisional application may establish that the invention was either actually reduced to practice or constructively reduced to practice, the declaration is still devoid of factual statements and/or evidence that establish that diligence existed from a date prior to the effective dates of the references to the filing date of the provisional application. Additionally note, when applicant is relying upon conception and diligence, the declaration must set forth the acts relied upon as well as the dates when those acts were performed when attempting to show diligence.

In the response filed 3/2/2009, Applicants argue that "*The evidence provided shows a submission date of September 2000 and the Examiner can take note of the February 2001 filing date; filing a patent application within five months of an invention disclosure is prima facie evidence of diligence*".

In response, the fact that the application was filed within five months of the invention disclosure is not considered *prima facie* evidence. Applicants response and/or declaration fails

to set forth any facts or evidence that reasonable diligence was taken between a date prior to the effective dates of the references and the filing date of the provisional application. Note sections 715.07(a) and 2138.06 of the MPEP which set forth the standard for reasonable diligence. Also note in some instances a 2-day period lacking activity has been found to be fatal (See MPEP 2138.06).

Response to Arguments

13. With respect to the 35 USC 103 rejections of record including the combination of the references of Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323) taken further in view of the additional references of record, Applicant argues that the rejections are improper for the following reasons:

i) Walt does not teach a plurality of different geometric shapes.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the combination of the reference of Walt et al. with any of Felder et al., Chang et al. or Ravkin et al. that suggest the use of geometric shapes.

ii) Walt does not teach a sensor having first and second portions of different shape:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the combination of the reference of Walt et al. with any of Felder et al., Chang et al. or Ravkin et al. that suggest the use of first and second portions of different shape.

iii) Walt does not teach curing to impart a shape:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the combination of the reference of Walt et al. with any of Felder et al., Chang et al. or Ravkin et al. taken further in view of Peters et al. or Kaetsu et al. that address curing a polymer to form a shape.

iv) Walt teaches discrete sites:

In response, while the sites may be discrete, the placement of the sensing elements at the sites are random just as is required of the instant application (See column 15, lines 64-66 of Walt).

v). Felder does not teach different geometric shapes:

In response, the reference of Felder discloses different shapes (See column 8, lines 55-61).

vi) Felder does not teach a sensor having first and second portions of different shape:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the combination

of the reference of Walt et al. with any of Felder et al., Chang et al. or Ravkin et al. that suggest the use of first and second portions of different shape.

vii) Felder teaches discrete sites:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the reference of Walt et al. that discloses the placement of the sensing elements at the sites are random just as is required of the instant application (See column 15, lines 64-66 of Walt).

viii) The reference of does not teach the use of shape to determine analyte binding:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the combination of the references of Walt et al. with Felder or Chang or Ravkin suggest the use of different shapes. The reference of Wang is cited merely to evidence that specific shapes are known in the art other than beads.

ix) The reference of Peters does not remedy the defect of Walt, Felder and Wang and is nonanalogous art:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the reference of Peters is relied upon to evidence ways that art conventional in the art for forming a sensing element with receptors embedded therewith.

x) The references of Dakss and Pope are nonanalogous art:

In response, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) and it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Examiner stresses that the reference of Walt is concerned with immobilization of the sensing particles (10) with respect to support (212 (fiber optic bundle)). Column 17, line 47, to column 18, line 12, lists a number of methods used to immobilize the particles (10) to the ends of the bundle (212). While using a cured liquid composition, the reference does not disclose that the sensing elements are disposed on or at an exterior surface of the cured liquid composition. As a result, the Examiner cited the reference of Pope to evidence that it is known to one of ordinary skill in the art to immobilize a sensing particle (11) to the end of an optical fiber (12) using an adhesive material (15). One of ordinary skill in the art would have clearly recognized that the particles of Walt could be immobilized using an adhesive as taught by the reference of Pope since the reference of Walt clearly contemplates alternative means for immobilization of sensing particles on the ends of optical fibers. With respect to the reference of Dakss, this reference was cited to evidence that

it is known in the art when using an adhesive to immobilize a particle on the end of an optical fiber to employ adhesives that encompass cured liquid compositions. In this case, the reference of Dakss is considered to be within the field of endeavor of the inventors of the reference of Walt because the reference concerns immobilization of a particle on the end of an optical fiber while maintaining the optical integrity of the sensing system. Also note the limitation disposed on or at the exterior surface of the cured liquid composition appears to be an immobilization step used to secure the sensing elements with respect to a supporting member (See claim 76). Note, page 11, lines 14-16, of Applicants' own specification states "*The sensing elements may be individually prepared and used to form a sensor. The sensor may be formed by immobilizing the sensing elements in or on a supporting material*". The Examiner maintains that immobilization of the sensing particles or elements of the modified primary reference of Walt et al. as suggested by the references of Pope and Dakss clearly address and meet the claim limitations recited in claim 76. With respect to claim 50, while not specifically limited to this claim language, claim 50 is met by this specific prior art rejection because the claim includes the language comprising and does not preclude the use of an immobilization step as suggested above.

xi) The Examiner misunderstands the case law. Applicants stress "The Examiner argues that the In re Keller and In re Merck & Co. cases support the legal proposition that one cannot attack the references individually. This is not correct. These cases apply to the situation where only one reference is rebutted and where the applicant remains silent on the other references in the combination. This is not the case here. Applicants have provided an argument regarding the primary reference (Walt) and each of the other references (Felder, Chang, Ravkin, Pope, Dakss, Peters, Kaetsu and Wang). Applicants have highlighted the deficiencies in Dakss (and pointed

out that Pope, Peters and Kaetsu do not remedy these deficiencies). Applicant has argued that Felder, Chang and Ravkin cannot be combined with Walt without a basis for the combination. This is consistent with more recent Federal Circuit precedent states that references must be evaluated individually for their specific motivation to one skilled in the art, without hindsight, before the combination can be made. In re Rouffet, 149 F.3d 1350, 476 USPQ2d 1453, 1458 (Fed. Cir. 1998). In any further office action, the Examiner must respond to both Applicants' analysis of Keller and Merck, as well as Applicants' citation to Rouffet".

In response to Applicants' demand that the Examiner respond to comment 4) above, the Examiner would like to point out that Applicants' have advanced a plurality of arguments on the record, some of which do address the obviousness of the combination of the references. However, some of the arguments merely attack a reference individually stating that the reference does not disclose the limitations of a claim (See Applicants comments concerning the Dakss reference in the response filed 7/16/2008). In this case, Applicants do remain silent with respect to the disclosures of the other references used in the combination. For example, Applicants' comments are silent with respect to the fact that the reference of Walt et al. discloses immobilization of the sensing elements on a supporting member as required of claim 76. With respect to In re Rouffet, the Examiner would like to first point out that the correct cite is 47 USPQ2d 1453 rather than 476 USPQ2d 1453. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include

knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the Examiner is of the position that the prior art of record and the rejection of record clearly sets forth the specific motivation to one skilled in the art, without hindsight. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As stated numerous times above, the combination of the prior art references is within the purview of one having ordinary skill in the art at the time the invention was made. The examiner would like to stress that the reference of Walt et al. clearly discloses distinguishing between a plurality of sensing elements in an array using different sizes of sensing elements (See column 18, lines 48-58, and column 19, lines 6-13). The references of Felder, Chang and Ravkin evidence that it is known in the art of sensing elements to distinguish between a plurality of sensing elements in an array using sensing elements of different size or shape (See column 8, lines 49-56, of Felder et al.; column 3, lines 33-39, of Chang et al.; and paragraphs [0096], [0137] and [0139] of Ravkin et al.). As stated previously, one of ordinary skill in the art would have recognized in view of these disclosures, not applicants' specification, that sensing elements of different shape could be used in the system of the reference of Walt et al. rather than sensing elements of different size.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner
Art Unit 1797

WHB